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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,075	08/22/2003	Vijaya Juturu	NUTRI.027A	9604

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,075

Applicant(s)

JUTURU ET AL.

Examiner

Raymond J Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-35, 69 and 70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-35 and 69 is/are rejected.
- 7) ☒ Claim(s) 70 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 32-35, 69 AND 70 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment and Terminal Disclaimer filed January 10, 2005 have been received and entered into the application. Accordingly, claims 32 and 33 have been amended; claims 65-68 have been canceled; and claims 69-70 have been added.

In order to clearly demarcate the pending claims from those claims that have been canceled, it is requested that a new claim set be submitted in which the text of the canceled claims is *not* set forth, i.e., a claim set which sets forth "1-31 (canceled), etc. See, for example, 37 CFR § 1.121(c)(1).

In view of the acceptable nature of the Terminal Disclaimer as well as the cancellation of claims 65-68, the rejection of claims 32-35 and 65-68 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-12 of U.S. Patent No. 5,707,970 (McCarty et al. '970) or claims 8-12 of U.S. Patent No. 6,156,735 (McCarty et al. '735) in view of Speck (U.S. Patent No. 6,066,659), Harrison's Principles of Internal Medicine ("Harrison's") and Levere et al. (U.S. Patent No. 5,217,997), as set forth in the previous Office action dated October 8, 2004 at pages 5-8, is withdrawn.

Claim Objection

Newly added claim 70 is objected to as depending from a rejected based claim, i.e., claim 32 (see below), but is otherwise in condition for allowance. None of the references of record teach or would have suggested that an arginine silicate complex reduces urinary albumin levels, i.e., the references are silent with respect to the effect of arginine silicate complex, or any component thereof, on urinary albumin levels.

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Claim Rejection - 35 USC § 103

Claims 32-35 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCarty et al. (U.S. Patent No. 5,707,970) in view of Speck (U.S. Patent No. 6,066,659), Harrison's Principles of Internal Medicine ("Harrison's") and Levere et al. (U.S. Patent No. 5,217,997), each of record, for the reasons of record as set forth in the previous Office action dated October 8, 2004 at pages 2-5, as applied to claims 32-35 and 65-68.

Newly added claim 69 is properly included in the present rejection because from McCarty et al., it would have been obvious that the arginine silicate complex of the present claim would provide an increase in vascular relaxation. The basis for this conclusion is (i) arginine is contained in the arginine silicate complex; McCarty et al. disclose that arginine is a precursor for nitric oxide (col. 1, lines 52-53); and McCarty et al. disclose that nitric oxide exerts vasodilatory effects (col. 1, lines 55-56).

Applicants' remarks at pages 9-13 of their amendment have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

The following portion of Applicants' response (page 11, first full paragraph) is deemed representative of their position that the present finding of obviousness is not proper:

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Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Kotzab, 217 F.3d 1365 (Fed. Cir. 2000). Applicants submit that the Examiner has pointed to no motivation to modify the reference teachings to arrive at the claimed method of treating diseases secondary to cardiovascular disease. All of the references are completely silent as to any benefits the administration of arginine-silicate-inositol complex might evince in ameliorating the symptoms or underlying diseases secondary to coronary vascular disease. Moreover, none of the cited references describe, suggest, or appreciate the role of arginine-silicate-inositol in treating diseases secondary to coronary vascular disease. A skilled artisan, therefore, would have no motivation, based upon the teachings of the cited references, to administer arginine-silicate-inositol to treat, for example, nephrosclerosis, microvascular complications, macrovascular complications, and abnormal lipid profiles as is presently claimed.

In response thereto, the Examiner acknowledges that there must be some motivation to do what Applicants are claiming and that such motivation must not be found in Applicants' disclosure. It is not required, however, that such motivation be expressly disclosed in the references relied upon to establish that the claimed subject matter would have been obvious. MPEP § 2144 states:

"The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed.

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Cir. 1988) (references do not have to explicitly suggest combining teachings); *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present convincing line of reasoning supporting rejection); and *Ex parte Levensgood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning).”(emphasis added).

While the references do not expressly disclose the modifications as proposed by the Examiner (see the previous Office action at pages 4-5), the burden of establishing a *prima facie* case of obviousness has nevertheless been met because (i) a convincing line of reasoning supporting the rejection has been set forth, see *Clapp*, supra, and/or (ii) logic and sound scientific reasoning has been relied upon, see *Levensgood*, supra. Applicants' arguments that the references fail to teach or suggest the presently claimed subject matter, in light of the Examiner's reasons to the contrary of such arguments, are therefore not deemed persuasive.

Applicants have also argued that the present conclusion of obviousness is based on impermissible hindsight reconstruction of the presently claimed subject matter. In response thereto, it is pointed out that it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as, as is here the case, that it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

With respect to the Examiner's conclusion that the treatment of hypertension would have been obvious from the teaching of the references relied on, Applicants urge that such conclusion is in error because Levere et al. only describe the use of arginine alone and not an arginine

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silicate complex. Applicants allege that because arginine is different than an arginine silicate complex, the effects of arginine could not be extrapolated to the effects of an arginine silicate complex. It remains the Examiner's position, however, that because arginine is a part of the arginine silicate complex, the known effects of a member of that complex would have been expected to contribute to the over-all effect of the complex as a whole. This is especially true in view of the express teaching of McCarty et al. that the arginine-silicate complex is useful as a source of arginine (previous Office action at page 6, lines 4-5). Also, while hypertension is not a condition that is presently claimed, it remains integral to the Examiner's conclusion of obviousness that the arginine silicate complex would have been expected to be useful for the purposes claimed because, as set forth by the Examiner at pages 4-5 of the previous Office action: "As evinced by claim 33, claim 32 reads on the treatment of nephrosclerosis. The skilled artisan would have appreciated that the arginine silicate inositol complex of McCarty et al. could be used to treat nephrosclerosis because (a) Harrison's teaches that the major goal of therapy for nephrosclerosis is the control of hypertension (page 1321, column 2, second full paragraph) (b) as noted above, McCarty et al. teach that the arginine silicate inositol complex is a useful source of arginine and (c) Levere et al. teach that arginine may be used to treat hypertension (see, for example, the abstract)". The Examiner stands by his finding that such would have rendered the presently claimed subject matter obvious to one of ordinary skill in the art.

Finally, Applicants have argued that the references fail to teach all of the claimed elements. In particular, Applicants argue that the references fail to teach or suggest "identifying an individual suffering from a disease secondary to coronary vascular disease". The Examiner, however, cannot agree because, for the reasons above and already of record, the treatment of an

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individual suffering from a disease secondary to coronary vascular disease would have been obvious to one of ordinary skill in the art. The step of identifying such a patient would also have been obvious because the artisan would necessarily first need to establish that a patient was in need of treatment for a disease secondary to coronary vascular disease before the patient was actually treated.

Accordingly, for the above reasons, the claims are deemed properly rejected.

None of the claims are allowed.

Applicants' amendment necessitated the new ground, i.e., new grouping of rejected claims, of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

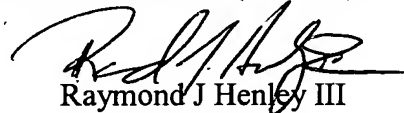
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J Henley III
Primary Examiner
Art Unit 1614

February 3, 2005